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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/756,765	01/14/2004	Per Egnelov	030481-0212	1510

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EXAMINER	
MALLARI, PATRICIA C	

ART UNIT	PAPER NUMBER
3735	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/756,765	EGNELOV ET AL.	
	Examiner	Art Unit	
	PATRICIA C. MALLARI	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 January 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-11,14-16 and 20-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *9,11,15 and 16* is/are allowed.

6)☒ Claim(s) *1,3-8,10,14 and 20-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 January 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The finality of the previous Office action, filed 10/30/07, is hereby withdrawn because claim 20 was not addressed in that Office action. This is a final Office action. Claim 20 is rejected under 35 U.S.C. 102(b). See the rejection below.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-8, 10, 14, and 20-23 are rejected under 35 U.S.C. 102(b) as being unpatentable over US Patent No. 4,894,052 to Crawford. Crawford discloses an indicator system comprising a body having a passage passing through the body, a duct 20, 20a extending in the body, and a hemostatically sealed blood accommodating chamber 26 (see entire document, especially fig. 4; col. 6, lines 3-51 of Crawford). An insertion tube 11, 11a comprises a distal end adapted to be positioned inside a blood vessel, fluid communication pathway between an uncovered liquid inlet opening 21a near a distal end of the insertion tube and the duct 20, and an opening 12a at the extreme end of the distal end portion (see entire document, especially figs. 2 and 4; col. 5, lines 33-35; col. 6, lines 3-51 of Crawford). A window 14 comprises an at least semi-transparent section configured to enable visual observation of blood entering into the duct via the inlet opening when the inlet opening is located inside the blood vessel (see

entire document, especially figs. 2 and 4; col. 4, lines 45-50; col. 5, lines 15-23 of Crawford). An elongated member 24 is adapted to be threaded in a substantially straight path through the passage and fluid communication pathway between a distal end of the insertion tube and a proximal end of the body, and an outer dimension of the elongated member and an inner dimension of the insertion tube are substantially equal to each other and are configured such that flow of blood between the outer and inner dimensions is prevented when the elongated member is inserted into the insertion tube (see entire document, especially fig. 4; col. 6, line 52-col. 7, line17 of Crawford). The system of Crawford is capable of visually indicating a pressure of blood inside a blood vessel in that the flow of blood into the catheter is an indicator of blood pressure in the vessel.

Regarding claim 3, the duct opens into the chamber 26 via an aperture having a spill over edge, the edge being formed by the wall of the syringe expanding from a smaller to a larger diameter. The device is capable of being positioned such that the aperture is located at a level above a bottom of the chamber such that return flow of the blood back to the chamber is prevented (see entire document, especially fig. 4 of Crawford).

Regarding claim 4, the chamber 26 is located in the body and further comprises the insertion tube 11, 11a extending distally of the body (see entire document, especially fig. 4 of Crawford).

Regarding claim 5, the inlet opening 21a is located on a side of the insertion tube (see entire document, especially fig. 4 of Crawford).

Regarding claim 6, the device is capable of being positioned such that the duct extends vertically to an aperture opening into the chamber (see entire document, especially fig. 4 of Crawford).

Regarding claim 7, the duct extends horizontally above at least a portion of the chamber to an aperture opening into the chamber (see entire document, especially fig. 4 of Crawford).

Regarding claim 8, the duct 20, 20a exhibits a varying cross-section over its length (see entire document, especially fig. 4 of Crawford).

Regarding claims 10 and 14, the elongated member projects distally past the extreme end of the distal end portion of the insertion tube (see entire document, especially fig. 4; col. 6, line 52-col. 7, line 17 of Crawford). With further regard to claim 10, the body may instead be considered to have a duct 17, 17a extending in the body and a hemostatically sealed blood accommodating chamber 20, 20a, wherein the insertion tube comprises a fluid communication pathway between an uncovered liquid inlet opening 12a near a distal end of the insertion tube and the duct (see entire document, especially figs. 2 and 4; col. 6, lines 64-69 of Crawford).

Regarding claim 20, Crawford further discloses providing the indicator system as described above, positioning the distal end portion inside the blood vessel, and indicating the pressure (see entire document, especially col. 5, lines 2-23; col. 6, lines 3-30 of Crawford), wherein the appearance of blood in the chamber indicates blood pressure in the blood vessel. With further regard to the indicator system, the passage and fluid communication pathway are adapted to permit the elongated member 24 to be

threaded in a substantially straight path there through between a proximal end of the body and a distal end of the insertion tube to plug, at least in part, the opening at the extreme end of the distal end portion (see entire document, especially fig. 4; col. 6, lines 3-30; col. 6, line 52-col. 7, line 17 of Crawford).

Regarding claim 21, the elongated member dilator, wherein the term dilator appears merely to indicate a use of the elongated member. A dilator is something that makes something else wider or larger, and the elongated member of Crawford is certainly capable of such a use.

Regarding claims 22 and 23, the elongated member is a guide rod or guide wire (see entire document, especially col. 5, lines 50-55 of Crawford).

Response to Arguments

Applicant's arguments filed 1/28/08 have been fully considered but they are not persuasive.

With regard to claims 1 and 20, the applicants argue that the opening 21a of Crawford is enclosed and therefore covered by an outer wall 14a (see figure 4), such that an "uncovered opening" is not taught by Crawford. However, the needle or insertion tube 11 is removable from the catheter 14, and therefore the port or opening 21a may be uncovered, as claimed (see entire document, especially col. 5, lines 33-39; col. 8, lines 31-41 of Crawford). Therefore, Crawford does teach an uncovered liquid inlet opening near a distal end of the insertion tube.

With further regard to claim 1, the applicants further contend that Crawford's opening 21a does not enable visual observation to blood when the inlet opening is located inside the blood vessel because Crawford's opening 21a is covered, such that the position of the opening makes no difference as to whether blood may be observed. However, claim 1 fails to recite that the opening enables such visual observation. Claim 1 instead recites, "a *window* comprising an at least semi-transparent section configured to enable visual observation of blood entering into the duct via the inlet opening when the inlet opening is located inside the blood vessel" (emphasis added). The window of Crawford indeed allows the visual observation of any blood that may enter the duct via the inlet opening when the inlet opening is located inside the vessel. Additionally, blood is certainly capably of entering the inlet opening when the inlet opening is located inside the vessel.

With regard to claim 20, the applicants assert that the claim recites that the opening at the extreme distal end be plugged so that pressure is indicated. The claim fails to include such a recitation. Claim 20 claims a method comprising providing an indicator system comprising a passage and fluid communication pathway, "wherein the passage and the fluid communication pathway are *adapted* to permit the elongated member to be threaded in a substantially straight path there through between a proximal end of the body and a distal end of the insertion tube to plug the opening at the extreme end of the distal end portion" (emphasis added). A recitation that the passage and fluid are adapted to permit the elongated member to plug the opening is not the same as requiring that the opening be plugged. Crawford shows such a indicator

system, having a passage and fluid communication pathway so shaped and sized, or adapted, to permit the elongated member to plug the opening at the extreme end (see entire document, especially figure 4; col. 5, line 46-col. 7, line 17 of Crawford). Additionally, Crawford discloses advancing the elongated member 24 from its retracted state, wherein the retracted state is that shown in figure 4 of Crawford) until its far end 28 is properly positioned within the blood vessel (see entire document, especially col. 6, lines 52-60 of Crawford) and further states that the needle 11a is occluded by the guide wire 24 (see entire document, especially col. 6, line 61-col. 7, line 17 of Crawford). Therefore, Crawford teaches providing an indicator system as claimed in claim 20.

Therefore, the rejection of claims 1, 3-8, 10, 14, and 20-23 under 35 U.S.C. 102(b) as being anticipated by Crawford stands.

Allowable Subject Matter

Claims 9, 11, 15, and 16 are allowed. The allowability of claims 9 and 15 was first addressed in an Office action filed 4/20/05. The allowability of claims 11 and 16 was first addressed in Office action filed 6/30/06. The reasons for allowance of claims 9, 11, 15, and 16 were repeated in the Office action filed 5/22/07.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia C. Mallari whose telephone number is (571) 272-4729. The examiner can normally be reached on Monday-Friday 10:00 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert L. Nasser Jr/
Primary Examiner, Art Unit 3735

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